TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice *is hereby given in accordance with G.S. 150B-21.2 that the Commission for MH/DD/SAS intends to adopt the rules cited as 10A NCAC 26E .0601 - .0604.*

Proposed Effective Date: *October 1, 2006*

Instructions on How to Demand a Public Hearing: *A person may demand a public hearing on the proposed rules by submitting a request in writing to Cindy Kornegay, 3018 Mail Service Center, Raleigh, NC 27699-3018 by June 30, 2006.*

Reason for Proposed Action: *To establish a Controlled Substances Reporting System, as per G.S. 90-113.70. Session Law 2005-276 included legislation which instructs the Department of Health and Human Services to establish a reporting system of prescriptions for all Schedule II through V controlled substances. It is intended to improve the State's ability to identify controlled substance abusers or misusers and refer them for treatment, and to identify and stop diversion of prescription drugs in an efficient and cost-effective manner that will not impede the appropriate medical utilization of licit controlled substances.*

Procedure by which a person can object to the agency on a proposed rule: *The objection, reasons for the objection and the clearly identified portion of the rule to which the objection pertains, may be submitted in writing to Cindy Kornegay, 3018 Mail Service Center, Raleigh, NC 27699-3018, by August 14, 2006.*

Comments may be submitted to: *Cindy Kornegay, 3018 Mail Service Center, Raleigh, NC 27699-3018, phone (919) 715-2780, fax (919) 733-1221, email cindy.kornegay@ncmail.net*

Comment period ends: *August 14, 2006*

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-733-2721.

Fiscal Impact: A copy of the fiscal note can be obtained from the agency.

☒ **State**
☐ **Local**
☐ **Substantive (**>$3,000,000**)**
☐ **None**

CHAPTER 26 – MENTAL HEALTH: GENERAL

SUBCHAPTER 26E - MANUFACTURERS: DISTRIBUTORS: DISPENSERS AND RESEARCHERS OF CONTROLLED SUBSTANCES

SECTION .0600 CONTROLLED SUBSTANCES REPORTING SYSTEM

10A NCAC 26E .0601 SCOPE
The rules of this Section as well as the provisions of Chapter 90, Article 5E shall govern requirements for the controlled substances reporting system as set forth in G.S. 90-113.70.

Authority G.S. 90-113.70; 90-113.76.

10A NCAC 26E .0602 DEFINITIONS
(a) As used in this Section, the following terms shall have the meanings as specified:
(1) "Controlled substance reporting system" means the reporting system as set forth in Article 5E of Chapter 90.
(2) "ASAP" means the American Society for Automation in Pharmacy.
(b) Any term not defined in this Section shall have the same definitions as set forth in G.S. 90-87 and 90-113.72.

Authority G.S. 90-113.70; 90-113.76.

10A NCAC 26E .0603 REPORTING REQUIREMENTS
(a) All dispensers as defined by G.S. 90-113.72(4) shall submit data to the Department on the dispensing of controlled substances in Schedules II thru V.
(b) A dispenser of a Schedule II, III, IV or V controlled substance shall report the data as set forth in G.S. 90-113.73(b).

Authority G.S. 90-113.70; 90-113.73(b); 90-113.76.

10A NCAC 26E .0604 REQUIREMENTS FOR TRANSMISSION OF DATA

(a) Each dispenser shall transmit to the Department the data as set forth in GS 113.73. The data shall be transmitted in the most recent format as set forth in the ASAP Telecommunication Format for Controlled Substances, published by the American Society for Automation in Pharmacy.

(b) The dispenser shall transmit the data electronically unless the Department approves a request for submission on paper as set forth in Paragraphs (e) and (f) of this Rule.

(c) The dispenser's electronic transfer data equipment including hardware, software and internet connections shall be in compliance with the Health Insurance Portability and Accountability Act as set forth in 45 CFR, Part 164.

(d) Each electronic transmission shall meet data protection requirements as follows:

(1) Data shall be at least 128B encryption in transmission and at rest; or

(2) Data shall be transmitted via secure file transfer protocol. Once received, data at rest shall be encrypted.

(e) The data may be submitted on paper, if the dispenser submits a written request to the Department and receives prior approval.

(f) The Department shall consider the following in granting approval of the request:

(1) The dispenser does not have a computerized record keeping system.

(2) The dispenser is unable to conform to the submission format required by the database administrator without incurring undue financial hardship.

(g) The dispenser shall report the data on the 30th day of each month for the first 12 months of the system's operation, and on the 15th day and 30th day of each month thereafter. If the 15th or the 30th day does not fall on a business day the dispenser shall report the data on the next following business day.

(h) The Department shall provide reports to the Commission concerning the outcomes of the implementation of the controlled substances reporting system. The reports shall be made to the Commission six and 12 months after the reporting system is implemented.

Authority G.S. 90-113.70; 90-113.73; 90-113.76.